July 25, 2000

MEMORANDUM

SUBJECT: **Oxamyl** (103801) Reregistration Case No. 0253. **Revised** Anticipated Residue and Acute and Chronic Dietary Exposure Estimates. Barcode D267627.

FROM: John S. Punzi, Ph.D., Chemist
Reregistration Branch 2
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division (7509C)

TO: Christina Jarvis, Risk Assessor
Reregistration Branch 2
Health Effects Division (7509C)

Attached is a second revision of the Anticipated Residue and Acute and Chronic Dietary Exposure Estimates for the Oxamyl Reregistration Eligibility Decision (RED) document. This chapter was revised after consideration of the registrant's response to the "error only" comment period following their review of the preliminary RED Chapters and Risk Assessment. Anticipated residues for pineapple and apple, and processing factors for baked and canned food forms were reassessed based on information provided by the registrant, the Pineapple Growers Association, and the Apple Growers Association. Preliminary, single serving, residue monitoring results from the 1999 USDA-Pesticide Data Program have become available and were considered for non-blended forms of apple and translated to pear. The Carbamate Market Basket Survey Task Force has completed a report which generally supports the PDP data however the data are presently being reviewed and have not been used for this assessment.

Action Requested

In support of the reregistration of Oxamyl, chronic and acute dietary exposure calculations were performed. This memorandum describes the data used to generate the anticipated residue estimations that were subsequently used for the exposure estimates and summarizes the results of a Tier 3 dietary risk assessment for oxamyl.

Executive Summary

Acute and chronic dietary exposures to Oxamyl from all current registered uses are below the Agency's level of concern.

The estimated acute dietary exposures to Oxamyl, considering all registered uses, at the 99.9th percentile ranged from a low of 0.000230 mg/kg body wt/day (23% aPAD) for males ages 13-19 to a high of 0.000807 mg/kg body wt/day (81% aPAD) for children ages 1-6. At the 99th percentile the aPAD ranged from ~8% (several subpopulations) to 28% (children ages 1-6).

The chronic dietary exposures to Oxamyl, considering all registered uses, ranged from a low of 0.000022 mg/kg body wt/day (2% cPAD) for males ages 13-19 years to a high of 0.000121 mg/kg body wt/day (12% cPAD) for children ages 1-6 years.

A substantial contributor to the estimated exposure for children ages 1-6 in this current assessment was found to be from apples. It should be noted that the anticipated residues for apple commodities are derived from single serving 1999 PDP data and the residue range and frequency is consistent with those found in the Carbamate Market Basket Survey Task Force Report (~7/2000). PDP data showed 6.3% of the single serving apple samples to have residues of Oxamyl ranging from 0.017 ppm to 0.056 ppm. The Carbamate Market Basket Survey showed 5% of the apples contained Oxamyl ranging from 0.001 ppm to 0.038 ppm.

Dietary Exposure Summary (includes all crops for which Oxamyl is currently registered)

Population	Acute Dietary (99.9th percentile)		Chronic Dietary	
	Exposure (mg/kg/day)	%PAD	Exposure (mg/kg/day)	%PAD
U.S. population	0.000433	43	0.000043	4
All infants (<1 year)	0.000382	**38**	0.000112	11
Children (1-6 years)	0.000807	**81**	0.000121	12
Children (7-12 years)	0.000412	41	0.000061	6

Population	Acute Dietary (99.9th percentile)		Chronic Dietary	
	Exposure (mg/kg/day)	%PAD	Exposure (mg/kg/day)	%PAD
Females (20+ years)	0.000391	39	0.000034	3
Males (13-19 years)	0.000230	23	0.000022	2
Males (20+ years)	0.000321	32	0.000026	3

Toxicological Information

The toxicological data summarized below was derived from the HIARC, FQPA, and TOX Chapter documents dated 8/31/99, 9/13/99, and 10/13/99 respectively. With the exception of the oral and inhalation LD_{50} studies, other acute studies have demonstrated that Oxamyl has low acute toxicity by other routes of administration. In an acute neurotoxicity study in rats, neurobehavioral effects were observed at a dose level of 0.75 mg/kg/day (females) and 1 mg/kg/day (males). In the dietary subchronic neurotoxicity study the same types of findings were observed at higher doses, males (14.9 mg/kg) and females (19.9 mg/kg) with a NOAEL of 2.1 mg/kg (males). Neurotoxic effects were also seen in other studies.

No dermal toxicity was observed in a 21-day rabbit dermal toxicity study; however, systemic toxicity related to blood and brain acetyl cholinesterase inhibition (ChEI) was observed in females at 75 mg/kg dose level. No developmental toxicity was seen at the highest dose tested (4 mg/kg) following in utero exposure to rabbits. Following in utero exposure to rats, decreases in fetal body weights were seen in the presence of maternal toxicity. In the two-generation reproduction study offspring toxicity was seen only in the presence of parental/systemic toxicity at the highest dose tested (5.2 mg/kg). Therefore, there was no indication of increased susceptibility following exposure to Oxamyl.

An acute RfD was derived from an acute neurotoxicity study in rats. The NOAEL was 0.1 mg/kg/day and the LOAEL was 1.0 mg/kg/day in males and 0.75 mg/kg/day in females. The endpoint was based on plasma, red blood cell, and brain ChEI.

Generally, a NOAEL/LOAEL from a chronic study is selected for establishing the chronic RfD. However, for Oxamyl, the HIARC selected a NOAEL from an acute neurotoxicity study based on weight of the evidence of the toxicity data. Data to support the decision include: the measurement of ChEI was not conducted at the peak time in chronic studies, the acute NOAEL (0.1 mg/kg) is also protective of any maternal/developmental effects and chronic exposure, and ChEI was reversible (not cumulative) as determined in a carbamate reversibility study. Therefore, there is high confidence in the

chronic RfD derived from the acute neurotoxicity study in rat.

In *in vitro* studies, Oxamyl is not mutagenic in the Ames test (bacteria), not mutagenic in mammalian cell culture, did not induce chromosomal aberrations in Chinese hamster ovary cells, negative for inducing DNA damage/repair, and does not cause unscheduled DNA damage in primary rat hepatocytes.

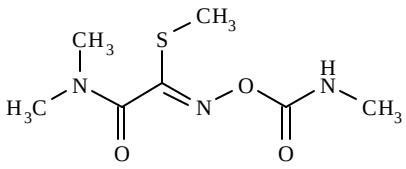
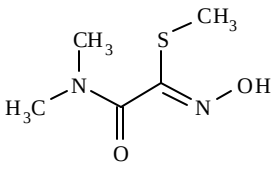
The FQPA Safety Factor Committee concluded that the safety factor should be removed for Oxamyl because the toxicology database is complete for FQPA safety factor assessment. The HIARC concluded that the toxicity data provide no indication of increased susceptibility of young rats or rabbits to Oxamyl and determined that a developmental neurotoxicity study is not required. Therefore, for Oxamyl the population adjusted dose (PAD) is equal to the RfD.

Table 1 Toxicological Parameters

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	Acute Neurotoxicity NOAEL=0.1 UF=100 FQPA=1	LOAEL = 0.75 mg/kg/day is based on clinical signs, and decreased plasma, red cell and brain cholinesterase inhibition in females	Acute Neurotoxicity - Rat
	Acute RfD = 0.001 mg/kg		
Chronic Dietary	NOAEL=0.1 UF=100 FQPA=1	LOAEL = 0.75 mg/kg/day is based on clinical signs, and decreased plasma, red cell and brain cholinesterase inhibition in females	Acute Neurotoxicity - Rat
	Chronic RfD = 0.001 mg/kg/day		

Chemical Background

Chemical structures of Oxamyl and its oxime metabolite.

	
Oxamyl: methyl N',N'-dimethyl-N-[(methylcarbamoyl)-oxy]-1-thiooxamimidate	**Oxime metabolite**: methyl N',N'-dimethyl-N-hydroxy-1-thiooxamimidate

Oxamyl is a carbamate insecticide, acaricide, and nematocide. Oxamyl is applied preplant, at planting, or postemergence and is registered for use on apples, bananas, carrots, celery, citrus, cotton, cucumbers, eggplants, garlic, ginger, muskmelons (including cantaloupe and honeydew melon), onions (dry bulb), peanuts, pears, peppers, peppermint, pineapples, plantains, potatoes, pumpkins, soybeans, spearmint, squash, sweet potatoes, tobacco, tomatoes, watermelons, yams, and non-bearing apples, cherries, citrus, peaches, and pears. Oxamyl is sold in the U.S as a soluble concentrate under the trade name Vydate®. There are currently no residential uses of Oxamyl.

BEAD reports that total Oxamyl use is nearly 500,000 pounds of active ingredient (a.i.) per year. Cotton accounts for the majority of usage (300,000 pounds a.i. per year). Although cotton accounts for most of the usage, Oxamyl is used on only a small proportion of cotton sown area (7-11%), and is applied 1-2 times per season when it is used, usually at a rate of about 0.2 pounds a.i. per acre. When Oxamyl is used on other crops, it is applied 1-3 times per season at 0.2 -1 pound a.i. per acre.

Application rates range from <1 lb a.i./ A to 8 lb a.i./ A and maximum seasonal rates of 12 lb a.i./ acre season can be used for some crops. The PHI is generally 7-14 days (ginger (30 day PHI); yams (60 day PHI); and cucumber (1 day PHI) are notable exceptions).

Tolerances for residues of Oxamyl in/on plant commodities [40 CFR §180.303] are currently expressed in terms of the sum of the residues of Oxamyl and its oxime metabolite [methyl N',N'-dimethyl-N-hydroxy-1-thiooxamimidate] calculated as Oxamyl. This is due to field trial data collection methods which involve hydrolysis of Oxamyl to form the oxime prior to quantitation. Tolerances range from 0.1 ppm (potatoes and root crop vegetables) to 10 ppm (peppermint hay, spearmint hay, and pineapple forage).

For tolerance reassessment purposes, HED will recommend revocation of peanut forage, peanut hulls, pineapple forage, and soybean straw tolerances since they are no longer considered significant feed items. The tolerance for root crop vegetables will be revoked with the concomitant establishment of tolerances for carrots, ginger, onions (dry bulb), sweet potatoes, and yams. Tolerances to be proposed include cotton gin by-products. There are no outstanding residue chemistry data requirements.

The qualitative nature of the residue in animals is adequately understood based on studies with lactating goats and laying hens. Oxamyl was found to be metabolized rapidly and extensively in goats and hens; Oxamyl and its oxime metabolite were not detected in eggs, milk, or any tissue. The Agency has concluded that there is no reasonable expectation of finite Oxamyl residues of concern in animal commodities.

The qualitative nature of the residue in plants is adequately understood based on studies with alfalfa, apples, beans, cotton, oranges, peanuts, potatoes, tobacco, and tomatoes. Oxamyl was found to undergo hydrolysis of the methylcarbamoyl group to the oxime metabolite which then conjugates to form a glucoside. The oxime metabolite glucoside may undergo demethylation to form oximino methyl glucoside, and both glucosides may be incorporated into plant polysaccharides. Small quantities of N,N-dimethyl-1-cyanoformamide and demethylated Oxamyl have been detected in plant tissues.

Adequate methods are available for data collection and tolerance enforcement for plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a GLC method with flame photometric detection (sulfur mode), Method I, for the enforcement of tolerances for plant and animal commodities. This method involves alkaline hydrolysis to convert Oxamyl to the oxime metabolite; therefore, the method determines combined residues of Oxamyl and its oxime metabolite. The lower limit of method quantitation is usually reported as the "detection level" (0.02 ppm) in field trials.

The Metabolism Assessment Review Committee has concluded that the main metabolite of Oxamyl (oxime) is not likely to be a potent acetyl cholinesterase inhibitor and need not be included in the risk assessment from a toxicological perspective (DP Barcode D260911). Field trial data were used in this assessment and it should be noted that the residue data from field trials are for Oxamyl **and** oxime combined. Since it is presently not possible to estimate the ratio of Oxamyl to oxime from these field trials, the residues in/on these commodities were assumed to be entirely Oxamyl and consequently were considered to be very conservative. The residue data from PDP and FDA are for parent only (see discussion below)**.**

Consumption Data and Dietary Risk Analysis

HED is currently using software developed by Novigen Sciences, Inc. (DEEM™) to calculate acute and chronic dietary risk estimates for the general U.S. population and various population subgroups. The food consumption data used in the program are taken from the USDA Continuing Survey of Food Intake by Individuals (CSFII). The Agency is currently using 1989-92 consumption data within version 6.77 of DEEM™. Consumption data are averaged for the entire U.S. population, and within population subgroups such as "all infants" to support chronic risk assessment, but retained as individual daily consumption data points to support acute risk assessment (which is based on distributions of consumption estimates for either deterministic- or probabilistic-type exposure estimates). The DEEM™ software is capable of calculating probabilistic type risk assessments when appropriate residue data (distributions of residues) are available.

For acute risk assessments, a food consumption distribution is calculated for each population subgroup of interest based on one day consumption data. The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier I/II type) exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment. Exposure estimates are expressed in mg/kg bw/day and as a percent of the aPAD.

For chronic risk assessments, residue estimates for foods (e.g. apples) or food-forms (e.g. apple juice), are multiplied by the average consumption estimate of each food/food-form of each population subgroup based on consumption reported over 3 days. Exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD.

Acute Assessment:

The PDP and FDA databases report residues found in 5 lb. (PDP) and 20 lb. (FDA) composite samples. This manner of reporting may not represent high-end residues that could be found if individual units of fruits and vegetables were analyzed. Therefore this assessment uses statistical methodology for applying composite sample information to acute dietary risk assessments. This methodology extrapolates data on pesticide residues in composite samples of fruits and vegetables to residue levels in single servings of fruits and vegetables. Given the composite sample mean, the composite sample variance, the number of units in each composite sample, and assuming a lognormal distribution, it is possible to *estimate* the mean and variance of the pesticide residues present on single servings of fruits and vegetables and calculate a theoretical distribution. This information was incorporated into a probabilistic exposure estimation model, the Monte-Carlo method. This methodology has adequate accuracy when more than 30 composite samples have detectable residues (Use of Pesticide Data Program in Acute Risk Assessment - sent to Federal Register May, 1999). Commodities that are blended are not decomposited since the measured PDP levels are assumed to be representative of the actual range of residue.

Chronic Assessment:

For chronic risk assessment, reported residues were averaged, whether based on PDP, FDA, or field trials. If a commodity had no reported detections by the PDP and FDA programs, and the expectation of no detection was confirmed by field trial data, the weighted average of 1/2 LOD was used to account for possible exposure that could not be more precisely quantified. The weighted average estimate of %CT was incorporated into all chronic residue estimates.

Processing Factors:

Oxamyl residues may be either concentrated or reduced by drying (dried fruits), processing (juice, catsup, etc.), washing, peeling, and/or cooking. Processing factors for cottonseed, soybean, tomatoes, and pineapples were obtained from studies submitted to fulfill the residue chemistry data requirements

for 860.1520 and were incorporated into this assessment. Residue reduction due to processing were also obtained from studies of Methomyl degradation on apple (baking) and green beans (canning). Since Methomyl and Oxamyl are structurally related, it is likely that Oxamyl will degrade in a similar fashion. Furthermore HED believes that the degradation of these two carbamates by the process of baking and/or canning will result in the formation of compounds that are unlikely to be potent cholinesterase inhibitors. These reduction factors were applied to all "baked" and "canned" food forms (MRID 42810701, MRID 42896902). Default processing factors were used in all other cases.

Anticipated Residues

Oxamyl anticipated residue estimates, or ARs in this assessment are based primarily on three residue data sources: 1) field trial data, submitted by the registrant to support tolerances; 2) USDA PDP food sampling data; and 3) FDA surveillance monitoring data. The order of preference for the purpose of risk assessment is: PDP data > FDA data > field trial data. PDP data are preferred over FDA data because the statistical design of the PDP program is appropriate for dietary risk assessment because sampling is done at grocery store distribution points instead of directly from the field and because the foods are prepared before analysis as they would typically be before consumption (i.e. peeling, washing). Some commodities not sampled by the PDP program are assessed based on translation of data from PDP sampled commodities in the same crop group. Other results are taken from FDA surveillance data, or field trial data where available. Field trial residue data are generally considered by HED as an upper-end scenario of possible residues and are more suited to the requirements of tolerance setting than to the requirements of dietary risk assessment (when the most realistic estimate is desired).

All Oxamyl residue estimates for crop commodities are listed in Attachment 1. The following is a description of how the available data, listed in Attachment 2, were utilized on a crop by crop basis. Following the bolded heading are brief descriptions of the source of data used to generate the acute and chronic anticipated residues.

Both USDA and FDA monitoring use multiresidue methods (MRM) for quantitating Oxamyl residues in/on commodities in their pesticide monitoring programs. USDA PDP uses a MRM for Oxamyl and FDA employs a MRM for both Oxamyl and a second separate method for determination of the oxime metabolite. The field trial data were obtained with an analytical method which employs a hydrolysis step converting Oxamyl to the oxime and report the value as total Oxamyl. Although the residues of concern for tolerance enforcement are the sum of Oxamyl and oxime, the residues considered for dietary exposure should be based on Oxamyl alone since the oxime metabolite is not expected to be a ChEI inhibitor. For this assessment however, field trial data were used for cottonseed, eggplant, ginger, garlic, onions, peanuts, mint, and pineapple. Since it is presently not possible to estimate the ratio of Oxamyl to oxime from these field trials, the residues in/on these commodities were assumed to be entirely Oxamyl and consequently were considered to be very conservative.

Generally USDA PDP monitoring studies have shown Oxamyl to be present in/on only a few crops. Detectable residues are rare and at relatively low levels. However, PDP has found significant residues of Oxamyl in/on celery and apple. Oxamyl in/on celery was found in/on approximately 16% of the samples and ranged from 0.017 ppm to 0.28 ppm. Composite apple samples consistently demonstrate 3-4% detects at concentrations ranging from 0.014 ppm to 0.32 ppm. Other crops that PDP has sampled that showed residues above the LOD are apple juice, green beans, spinach, tomatoes, pears, cantaloupe, and winter squash. The frequency of occurrence of Oxamyl residues in/on these crops was <1%.

FDA monitoring data for Oxamyl has also shown residues to be present on only a few crops, rarely and at relatively low levels. Oxamyl was found in/on; honeydew, squash, watermelon, eggplant, sweet and hot pepper, pears, and apples. Apples, pears, and peppers consistently demonstrate detectable residues from year to year. Typical residue values ranged from 0.003-0.089 ppm for apple, 0.003-0.11 ppm in cantaloupe and 0.003-0.61 ppm for sweet pepper.

An example of the calculations performed to develop the input files and AR's for DEEM^{tm} is given at the end of Attachment 1.

Apple

Registered labels permit broadcast application to apples at a maximum single application rate of 2 lb ai/100 gallons. One application per season is permitted at this rate and the PHI is 14 days. The data set contains 70 detectable residues found in 1910 samples measured over 3 years in PDP monitoring (3.7%). DEEM input requires that distinct residue distributions be generated for non-blended (NB), partially blended (PB), and blended (B) food forms for apple. Table 1 lists the appropriate food forms and corresponding RDF file(s). Since USDA-PDP has provided preliminary "single-serving" residue data, decompositing was not needed to generate an appropriate RDF file for NB food forms of apple. The entire distribution of detects from the composite samples was used for PB food forms corrected for BEAD's maximum crop treated estimate (%CT). Chronic anticipated residue (AR) as computed from the average of the PDP detects corrected for BEAD's weighted average of %CT (11%).

Apple Juice

The data set contains 1 detectable residue from 1754 samples measured over 3 years in PDP monitoring (<1%). Presently apple juice is considered PB and an appropriate RDF file was generated using BEAD's likely maximum %CT data. Chronic AR was computed from the single detect, incorporating the weighted average of the %CT data.

Pear

Registered labels permit broadcast application to pears at a maximum single application rate of 2 lb ai/100 gallons. One application per season is permitted at this rate and the PHI is 14 days. The original data set contained 14 detectable residues from 1420 samples measured over a 2 year period from PDP monitoring (1%). Since USDA-PDP has provided preliminary "single-serving" residue data for apple, decompositing was not considered to generate an appropriate RDF file for NB food forms. Single serving data from USDA-PDP apple data was translated for NB food forms. DEEM inputs for pear food forms require that separate RDF files be generated for PB. Table 1 lists the appropriate food form and corresponding RDF files for pear. Chronic AR was computed from the average of the PDP detects incorporating BEAD's weighted average of %CT (1%). FDA data was included in Table 2 for reference. Anticipated residues for pear juice were translated from apple juice and a correction for the %CT was applied.

Banana/Plantain

Registered labels permit soil or foliar application to banana at a maximum single application rate of 2.4 g ai per corm. Applications up to 4 lb ai/A per season are permitted at this rate and the PHI is 1 day. The data set contains all non-detects from 1126 samples measured over 2 years in PDP monitoring (<1%). DEEM input requires that separate RDF files be generated for banana food forms (NB and PB); however in this case they are identical. Table 1 lists the appropriate food forms and corresponding RDF file. BEAD could not provide reliable data concerning %CT and a default of 100% was used for both acute and chronic calculations.

Cantaloupe, Honeydew, Pumpkin, Winter Squash, Summer Squash, Watermelon

Registered labels permit application by soil incorporation (4 lb ai/A) or broadcast application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 1 day. The data used for cantaloupe and winter squash, were translated to honeydew, pumpkin, and summer squash. The data set contains 1 detectable residue from 408 samples of cantaloupe (1 year) and 1 detectable residue from 970 samples of fresh winter squash (2 years) reported in PDP monitoring. Cantaloupe food forms for DEEM inputs require that two separate RDF files be generated for NB and partially blended PB forms. Table 1 lists the appropriate food form and RDF file. Since the number of detects was less than 30, decompositing was not performed. The entire distribution of data was used to generate an appropriate RDF file incorporating BEAD's maximum crop treated estimate. A chronic AR was computed from the average of the PDP detectable residues incorporating for BEAD's weighted average of %CT.

Carrot

Registered labels permit soil incorporation (8 lb ai/A) or foliar application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 8 lb ai/A and the PHI is 14 days. The data set contains all non-detects from 1888 samples measured over a 3 year period from PDP monitoring (<1%). Carrot food forms for DEEM inputs require that two separate RDF files be generated for NB and partially blended PB; however in this case they are identical. Table 1 lists the appropriate food form and corresponding RDF file. The entire distribution of data was used to generate an appropriate RDF file incorporating BEAD's maximum crop treated estimate. Chronic AR was computed from the average of the PDP detectable residues corrected for BEAD's weighted average of %CT (3%).

Celery

Registered labels permit soil incorporation (4 lb ai/A) or foliar application to celery at a maximum single application rate of 2 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 21 days. The data set contains 29 detectable residues found in 176 samples measured in a single year of PDP monitoring (16.5%). Celery food forms for DEEM input require that separate RDF files be generated for NB and PB. Table 1 lists the appropriate food forms and corresponding RDF file. Although the number of detects was one less than 30, decompositing was performed to generate an appropriate RDF file for non blended food forms. The entire distribution of detects was used for PB food forms corrected for BEAD's maximum crop treated estimate. The chronic AR was computed from the average of the PDP detects incorporating BEAD's weighted average of %CT (54%).

Citrus (includes Orange, Grapefruit, Lemon, Lime)

Registered labels permit foliar application or chemigation to citrus at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 7 days. The data set (orange) contains all non-detects from 1873 samples measured over 3 years in PDP monitoring (<1%). BEAD reports very low use in/on citrus with 2 % maximum on grapefruit and <1 % maximum on oranges. Orange data were translated to other forms. Citrus food forms for DEEM inputs require that two separate RDF files be generated for NB and PB; however in this case they are identical. Table 1 lists the appropriate food form and corresponding RDF file. The entire distribution of data was used to generate an appropriate RDF file corrected for BEAD's maximum crop treated estimate. The chronic AR was computed from the weighted average of the PDP non-detects (1/2LOD) incorporating BEAD's weighted average of %CT (1%).

Cottonseed

Registered labels permit broadcast application or chemigation for cotton at a maximum single

application rate of 1 lb ai/A. The maximum seasonal rate permitted is 4 lb ai/A and the PHI is 7 -14 days depending on the formulation. The data set contained 6 detectable residues from 22 field trials conducted in representative regions of the country. The application rate was 4-5 lb ai/A and the PHI 14 days. The residues of Oxamyl ranged from <0.02 ppm to 0.4 ppm in/on cottonseed and the average is 0.07 ppm. The DEEM inputs for cotton are considered blended and a point estimate is used (Table 1). The chronic AR was computed from the average of the PDP detects incorporating BEAD's weighted average of %CT (7%). Reference MRID 00113341, 41016701. Processing factors for cottonseed meal and cottonseed oil were obtained from MRID 42810701.

Cucumber

Registered labels permit soil incorporation (4 lb ai/A) or broadcast application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 1 day. The data set contains all non-detects from 173 samples measured over 5 years of FDA monitoring (<1%). Cucumber food forms for DEEM inputs require that two separate RDF files be generated for NB and PB. BEAD has provided %CT data for fresh and processed cucumbers allowing the latter to be used for the partially blended (canned) food forms. Table 1 lists the appropriate food form and corresponding RDF file. The entire distribution of data was used to generate an appropriate RDF file corrected for BEAD's maximum crop treated estimate. Chronic AR was computed from the average of the PDP detects corrected for BEAD's weighted average of %CT (14% fresh, 1% processed). PDP data for cucumber samples are not available and %CT for honeydew and winter squash are significantly different to allow translation.

Eggplant

Registered labels permit soil incorporation (2 lb ai/A) or broadcast application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 1-7 days depending on application. The data set contains 9 detects from 9 field trials conducted in representative regions of the country. The application rate was 6 lb ai/A and the PHI is 14 days. The residues of Oxamyl ranged from 0.08 ppm to 1.75 ppm in/on eggplant. The DEEM inputs for eggplant are considered NB and an appropriate rdf file was generated (Table 1). Chronic AR was computed from the average of the detects corrected for BEAD's weighted average of %CT. Reference MRID 00081618.

Garlic

Registered labels permit in-furrow treatment, irrigation or broadcast application at a maximum single application rate of 4 lb ai/A. The maximum seasonal rate permitted is 4.5 lb ai/A and the PHI is 14

days. The data were translated from onion corrected for %CT.

Ginger

Registered labels permit soil incorporation (4 lb ai/A) or broadcast application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 10 lb ai/A and the PHI is 30 days. The data set contains all non detects (<0.02 ppm) from 4 field trials conducted in HI. The application rate was 10 lb ai/A and the PHI 30 days. The DEEM inputs for ginger are considered NB and 100% CT was assumed (Table 1). Chronic AR was computed corrected for BEAD's weighted average of %CT. Reference MRID 41632701.

Mint

Registered labels permit soil or foliar application at a maximum single application rate of 3 lb ai/A. The maximum seasonal rate permitted is 4 lb ai/A and the PHI is 21 days. The data set contained 12 samples from field trials in Oregon. The application rate was 2-3 lb a.i./A with a total seasonal maximum ranging from 10-12 lbs a.i./A. The samples were taken at 21 days after the last application and all samples were <0.02 ppm, the reported LOQ for these trials. Chronic AR was computed from the average of the field trials corrected for BEAD's weighted average of %CT. Reference PP3E2860

Onion

Registered labels permit in-furrow treatment, irrigation or broadcast foliar application at a maximum single application rate of 4 lb ai/A. The maximum seasonal rate permitted is 4.5 lb ai/A and the PHI is 14 days The data set contained 26 detects from 51 field trials conducted in representative regions of the country. The application rate was 4-8 lb ai/A and the PHI 14 days. The residues of Oxamyl ranged from 0.02 ppm to 0.18 ppm in/on onions. The DEEM inputs for onion are considered B, NB, and PB, and an appropriate rdf file was generated (Table 1). Chronic AR was computed from the average of the PDP detects corrected for BEAD's weighted average of %CT. Reference MRID's 41402603, 42725406, 41936415, 41468008, 43365403.

Peanut

Registered labels permit soil incorporation or foliar application three and six weeks postemergence at a maximum single application rate of 3 lb ai/A. The maximum seasonal rate permitted is 5lb ai/A and the PHI is 30 days. The data set contained all non detects from 6 field trials conducted in representative regions of the country. The application rate was 5-11 lb ai/A and the PHI 30 days. The DEEM inputs for peanuts are considered B and an appropriate rdf file was generated (Table 1). Chronic AR was computed corrected for BEAD's weighted average of %CT. Reference MRID 41402609.

Peppers

Registered labels permit soil incorporation or foliar application at a maximum single application rate of 1 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is 7 days.
The data set contains 12 detectable residues from 314 samples measured over 5 years of FDA monitoring (~4%). Since FDA monitors and reports data separately for hot and sweet pepper, separate RDF files were generated. Pepper food forms for DEEM inputs require that two separate RDF files be generated for NB and PB however in this case they are identical. BEAD has provided % crop treated data for sweet peppers which was used for hot pepper. Table 1 lists the appropriate food form and corresponding RDF file. The entire distribution of data was used to generate an appropriate RDF file corrected for BEAD's maximum crop treated estimate. Chronic AR was computed from the average of the PDP detects corrected for BEAD's weighted average of % Crop Treated (18). PDP data for pepper are not available.

Pineapples

Registered labels permit soil incorporation or foliar application at a maximum single application rate of 4 lb ai/A. The maximum seasonal rate permitted is 8 lb ai/A and the PHI is 30 days. The data set contained 14 samples from field trials conducted in HI. The application rate was 2 lb ai/A with a total seasonal maximum ranging from 6-10 lbs ai/A. The samples were taken at 14-27 days after the last application. Residues of Oxamyl ranged from 0.02 ppm to 0.59 ppm and the average is 0.252 ppm. The Pineapple Growers Association report that 24% of the domestic crop is treated with Oxamyl. The registrant has provided the Agency with statistical data pertaining to Oxamyl usage on imported pineapple suggesting that only a small percentage of imported pineapple is expected to have been treated. FDA data was also evaluated for imported samples (all non-detects).
Given that approximately 80% of the pineapple consumption is from imported samples an rdf file was assembled as follows: Assuming 1000 samples comprise the rdf file; 800 are represented by imports and 200 domestic. Considering that 3% of the 800 import samples were assumed to have been treated with Oxamyl, it follows that the remaining import samples are not expected to have been treated and are assigned a value of zero. There were no detects in FDA monitoring for imported pineapple consequently the rdf file contains 24 import samples at ½ LOD and 776 samples at zero. The 200 samples representing the domestic fraction of the rdf file is comprised of 24% detects (48 samples) and 152 zeros. The residue values for the 48 samples were taken from the 14 field trial data points that were available using some data points more than once. The data were considered in order of appearance from the field trial data submission, in triplicate (3 x 14 data points). The remaining 6 data points used to comprise the entire list of 48 were taken in order of appearance from the data submission and the remaining were input as zeros. Processing factors were obtained from MRID 41632702.

Potatoes

Registered labels permit soil incorporation or foliar application at a maximum single application rate of 4 lb ai/A. The maximum seasonal rate permitted is 9 lb ai/A and the PHI is 7 days. The data set contains all non-detects from 1401 samples measured during 2 years of PDP monitoring (<1%). Potato food forms for DEEM inputs require that three separate RDF files be generated for NB, PB, and B. Table 1 lists the appropriate food forms and corresponding RDF file. Chronic AR was computed from the average of the PDP detects corrected for BEAD's weighted average of % Crop Treated (2%).

Sweet Potatoes

Registered labels permit at planting soil incorporation a maximum single application rate of 6 lb ai/A. The maximum seasonal rate permitted is 6 lb ai/A and the PHI is not specified. The data set contains all non-detects from 1202 samples measured during 2 years of PDP monitoring (<1%). Potato food forms for DEEM inputs require that three separate RDF files be generated for NB, PB, and B. Table 1 lists the appropriate food forms and corresponding RDF file. Chronic AR was computed from the average of the PDP detects corrected for BEAD's weighted average of % Crop Treated for potatoes (2%).

Soybeans

Registered labels permit at planting soil incorporation a maximum single application rate of 4 lb ai/A. The maximum seasonal rate permitted is 4 lb ai/A and the PHI is not specified. The data set contains all non-detectable residues from 690 samples measured during 1 years of PDP monitoring (<1%). All soybean food forms for DEEM inputs are considered B. Table 1 lists the appropriate food forms and corresponding RDF file if applicable. Monitoring data applied to blended forms of soybean does not incorporate crop treated data. Chronic AR was computed from the average of the data incorporating BEAD's weighted average of % Crop Treated (1%). FDA data for imported or domestic samples are unavailable. Processing factors were obtained from MRID 41572404.

Tomatoes

Registered labels permit soil incorporation or foliar application at a maximum single application rate of 2 lb ai/A. The maximum seasonal rate permitted is 8 lb ai/A and the PHI is 3 days. The data set contains 12 detects found in 1613 samples measured over 3 years in PDP monitoring (<1)%. Tomato food forms for DEEM inputs require that distinct RDF files be generated for NB and PB. Table 1 lists the appropriate food forms and corresponding RDF file. The entire distribution of detects was used for NB and PB food forms corrected for BEAD's maximum crop treated estimate. Chronic AR was computed from the average of the PDP detects incorporating BEAD's weighted average of % Crop Treated (11%). FDA data for imported samples only was included in Table 2 for reference. Processing studies which demonstrated residue reductions in processed tomato and are used in the DEEM analysis: Whole canned tomatoes 0.07, canned tomato juice 0.13, tomato paste 0.36, catsup 0.24, puree 0.16 (MRID 42725411).

Results/Discussion

This chapter was revised after consideration of the registrant's response to the "error only" comment period following their review of the preliminary RED Chapters and Risk Assessment. Anticipated residues for pineapple and apple, and processing factors for baked and canned food forms were reassessed based on information provided by the registrant; the Pineapple Growers Association; and preliminary, single serving, residue monitoring results from the 1999 USDA-Pesticide Data Program. Consequently the dietary exposure estimates were recomputed employing the revised residue data.

Acute and chronic dietary exposures to Oxamyl from all registered uses are below the Agency's level of concern.

The estimated acute dietary exposures to Oxamyl, considering all registered uses, at the 99.9th percentile ranged from a low of 0.000230 mg/kg body wt/day (23% aPAD) for males ages 13-19 to a high of 0.000807 mg/kg body wt/day (82% aPAD) for children ages 1-6. At the 99th percentile the aPAD ranged from ~9% (several subpopulations) to 28% (children ages 1-6).

The chronic dietary exposure considering all registered uses ranged from a low of 0.000022 mg/kg body wt/day (2% cPAD) for males ages 13-19 years to a high of 0.000121 mg/kg body wt/day (12% cPAD) for children ages 1-6 years.

A substantial contributor to the estimated exposure for children ages 1-6 in this current assessment was found to be from apples. It should be noted that the anticipated residues for apple commodities are derived from single serving 1999 PDP data and the residue range and frequency is consistent with those found in the Carbamate Market Basket Survey Task Force Report (~7/2000). PDP data showed 6.3% of the single serving apple samples to have residues of Oxamyl ranging from 0.017 ppm to 0.056 ppm. The Carbamate Market Basket Survey showed 5% of the apples contained Oxamyl ranging from 0.001 ppm to 0.038 ppm.

The amount of pesticide to which an individual is exposed to is determined by combining the consumption data and residue data. Qualitatively it follows that if there is high consumption of a type of food with a relatively low amount of pesticide the exposure would be similar to a type of food where a low consumption and a high pesticide level is found. The risk calculations are performed in a probabilistic fashion so that any of the consumers in the DEEM model have the same chance of eating a food type that has; not been treated (zero residue), treated but not detected (½ LOD); or demonstrable residues of oxamyl. Apples are an example of a food type that has low residue levels of Oxamyl and high consumption. Hence when combined with a low dietary toxicological endpoint, it becomes a significant contributor to the acute dietary risk. One of the limitations to our present model is that the consumption of an entire day of a particular type of food is added together then combined with the residue data. In other words if someone were to eat 3 apples in a single day our model

assumes they all have the same residue value. The DEEM model thus provides a conservative assessment for acute exposure to some foods.

Dietary Exposure Summary (includes all crops)

Population	Acute Dietary (99.9th percentile)		Chronic Dietary	
	Exposure (mg/kg/day)	%PAD	Exposure (mg/kg/day)	%PAD
U.S. population	0.000433	43	0.000043	4
All infants (<1 year)	0.000382	**38**	0.000112	11
Children (1-6 years)	0.000807	**81**	0.000121	12
Children (7-12 years)	0.000412	41	0.000061	6
Females (20+ years)	0.000391	39	0.000034	3
Males (13-19 years)	0.000230	23	0.000022	2
Males (20+ years)	0.000321	32	0.000026	3

List of Attachments

1. Anticipated Residues and Residue Distribution Files (RDF) for Oxamyl
2. Anticipated Residues Data
3. Acute Dietary Exposure Results (Oxamyl.AC4)
4. Chronic Dietary Exposure Results (Oxamyl.CHR)
5. R96 DEEM ^{tm} Input File (Oxamyl.R96)
6. RDF Files (26 Files)

Attachment 1. Anticipated Residues and Residue Distribution Files (RDF) for Oxamyl.
Note: The RDF file heading is included here but not the entire residue distribution. The complete files are listed in attachment 6.

Commodity (Reassessed Tolerance, ppm)	% Crop Treated Ave.	Max.	Data Source	Commodity* Classification	Food Forms	Acute AR or Acute Residue Distribution File (RDF)*	Chronic AR (Avg. %CT included, ppm)*
Apples (2)	11	18	PDP	NB	Uncooked, cooked, baked, boiled, fried	39NZ, 0@0.005, 397Z	0.002459
			PDP	PB	Canned/frozen	70NZ, 274@0.015, 1566Z	0.002459
			PDP	PB	Juice/juice concentrate	1NZ, 315@0.008, 1438Z	0.000913
			PDP	B	Dried	0.004028	0.002999
Pears (2)	1	2	PDP (single serving apple)	NB	Uncooked, cooked, baked, boiled	39NZ, 0@0.005, 397Z	0.000676
			PDP (apple juice)	PB	Juice	1NZ, 315@0.008, 1438Z	0.000092
			PDP	PB	Canned	14NZ, 15@0.010, 1391Z	0.000676
Bananas (0.3)	100	100	PDP	NB	Uncooked, cooked, baked, boiled, fried	0.0117	0.014605
			PDP	PB	Canned, juice, dried	0.0117	0.014605
Cantaloupes (2.0)	30	33	PDP (1998) and 1997, 1998 winter squash	NB	pulp	1NZ, 135@0.010, 274Z	0.004872
				PB	juice	1NZ, 135@0.010, 274Z	0.004872
Carrots (0.1)	3	6	PDP	NB	uncooked, cooked, baked, boiled	0NZ,112@ 0.014, 1776Z	0.000414
				PB	Canned, frozen	0NZ,112@ 0.014, 1776Z	0.000414

Celery (10)	54	65	PDP	NB	uncooked, cooked, baked, boiled	1000Z,2940@0.017 1,2121Z	0.020833
				PB	Canned, frozen	29NZ, 66@ 0.0171, 81Z	0.020833
Citrus (3)	1	2	PDP (Oranges)	NB	Peeled fruit-uncooked, cooked	0NZ, 18@0.01, 1874Z	0.000100
				PB	Peel/, Peeled fruit-canned	0NZ, 18@0.01, 1874Z	0.000100
				PB	Juice/Juice concentrate	0NZ, 18@0.01, 1874Z	0.000100
cottonseed (0.2)	7	11	FT	B	meal	0.0077	0.0049
cucumbers (2)	14	28	FDA	NB	uncooked	0NZ,45@0.003,128 Z	0.000329
	1	6		PB	Canned	0NZ,11@ 0.003 , 162Z	0.000035
Eggplants (2)	13	35	FT	NB	all forms	9NZ, 17@0.08, 0Z	0.076844
Ginger (0.1)	100 (HI only)		FT	NB	all forms	0.01	0.01
Garlic (0.1)	1	6	FT (bulb onion)	NB/PB	all forms	26 NZ, 25@0.01 799Z	0.002578
Honeydew (2.0)	12	24	PDP (1998) (winter squash, 97,98)	NB	uncooked	2NZ, 331@0.01, 1047Z	0.004035
onions (0.2)	6	19	FT	B	Dehydrated	0.010815	0.003991
				NB/PB	all other forms	26 NZ, 25@0.01 217Z	0.003991
peanuts (0.1)	<1	1	FT	B	all forms	0.000218	0.000218
mint	16	20	FT	B	All forms	0.002	0.0016

peppers (3, bell)	18	41	FDA sweet pepper	NB	uncooked, cooked, baked, fried	7NZ 63@0.0015 101Z	0.006021
				PB	Canned, frozen, cured	7NZ 63@0.0015 101Z	0.006021
peppers (5, non bell)	18	41	FDA hot pepper	NB	uncooked, cooked, baked, fried	5NZ 54@0.0015 84Z	0.010063
				PB	CANNED, FROZEN, CURED	5NZ 54@0.0015 84Z	0.010063
pineapples (1)	100		Field trials	PB	Dried, juice, canned, frozen	48NZ 24 @ 0.0015 928 Z	0.252
				NB	Uncooked, cooked, baked, boiled	48NZ 800@0.0015 152Z	0.252
Potatoes/ (0.1)	2	4	PDP	NB	White-peeled and white-whole: uncooked, cooked, baked, boiled, fried; white-peel only	0NZ 56@0.0127 1345Z	0.000254
				PB	White-peeled and white-whole: canned, frozen	0NZ 56@0.0127 1345Z	0.000254
				B	White-dry		0.0127
Sweet Potatoes/(0.1)	2	4	PDP	NB	incl yams: , cooked, baked, boiled, fried	0NZ 48@0.0082 1154Z	0.000164
				PB	incl yams: canned, frozen	0NZ 48@0.0082 1154Z	0.000164
pumpkin(2.0)	<1	1	PDP (cantaloupe, squash)	NB	cooked, baked, boiled, fried	2NZ, 138@0.01, 1240Z	0.001851

			PB	canned	2NZ, 138@0.01, 1240Z	0.001851
soybeans (0.1)	<1 1	PDP	B	all forms	0.002915	<0.000001
summer squash (2.0)	<1 1	PDP (winter squash)	NB	boiled, uncooked, cooked, baked, boiled, fried	2NZ, 453@0.010, 923Z	0.000751
			PB	FROZEN, CANNED, CURED	2NZ, 453@0.010, 923Z	0.000751
tomatoes(2)	8 11	PDP	PB	catsup, DRIED, JUICE, PASTE, PUREE, CANNED, FROZEN	12NZ 166@0.01 1435z	0.001338
			NB	UNCOOKED, COOKED, BAKED, FRIED	12NZ 166@0.01 1435z	0.001338
winter squash	<1 1	PDP	NB	ALL FORMS	1NZ, 10@0.010, 959Z	0.00158
watermelon	2 4	PDP (cantaloupe, winter squash)	NB	UNCOOKED	2NZ, 53@0.010, 1325Z	0.001091
			PB	JUICE	2NZ, 53@0.010, 1325Z	0.001091

* Abbreviations:

PDP	USDA Pesticide Data Program
FDA	FDA Surveillance Monitoring Program
PB	Partially Blended
NB	Not Blended
B	Blended
AR	Anticipated residue
NZ	Non Zeros
Z	Zeros
CT	BEAD estimate of % crop treated, lower number is a weighted average and the higher number represents a maximum likely value.

Example of Acute RDF File and Calculation of Chronic AR:

Commodity: PEAR
Food form: NB

PDP shows 14 detects out of 1420 samples:
0.12 ppm, 0.03 ppm , 0.15 ppm , 0.047 ppm , 0.058 ppm , 0.091 ppm , 0.042 ppm , 0.042 ppm, 0.058 ppm, 0.1 ppm, 0.017 ppm, 0.035 ppm, 0.12 ppm, 0.03 ppm.

The sum is 0.94 ppm.

The weighted LOD is 0.02 ppm.

To build the RDF file for the **ACUTE** calculations we want to estimate the number of samples that were theoretically treated with Oxamyl and the number of samples that were not exposed to the pesticide. This will establish the number of samples input at ½ LOD and the number that can be assigned zero.

The number of samples that were theoretically treated with Oxamyl are 1420 * (max % CT). In this case: 1420 * 0.02= 29 samples.

We have 14 detects, therefore (29-14)=15 is the number of samples that were theoretically treated with Oxamyl but the pesticide was not detected. Further, (1420-29)=1391 samples were not treated and assigned zero residue.

The abbreviated rdf heading in the above table (14NZ, 15@0.010, 1391Z) refers to 14 non zero residues, 15 at ½ LOD and 1391 zero residue.

To compute the **CHRONIC** AR we compute an average residue:

(sum of detects (ppm)+sum of samples at ½ LOD (ppm))/ total samples

In this case the number of samples at ½ LOD (and subsequently the number at zero) are computed with the weighted average of the % CT.

In the case of PEAR; 1391*0.01 = 14 samples are theoretically treated. Since we have 14 detects we have no samples at ½ LOD and the average residue is:

0.94/1391= 0.000676 ppm

Attachment 2
Anticipated Residues Data

Commodity	Data Source		Number of Samples	Detects	Residue Range (ppm)	Avg (+-SD) (ppm)	LOD (ppm)
Apples	PDP (94-96) 1999 single serving		1910 397	70 39	0.014-0.32 0.017-0.06	0.04 (04)	0.029
	FDA	Import	54	0	na	na	0.003
		US	328	4	0.003-0.089	na	0.003
Apple Juice	PDP (96-98)		1754	1	0.008-0.017	na	0.016
	FDA	Import	17	0	na	na	0.003
		US	83	0	na	na	0.003
Pears	PDP (97-98)		1420	14	0.017-0.15	0.07 (04)	0.020
	FDA	Import	65	0	na	na	0.003
		US	105	2	0.003-0.115	na	0.003
Bananas	PDP (94-95)		1126	0	na	na	0.029
	FDA	Import	154	0	na	na	0.003
		US	18	0	na	na	0.003

Cantaloupe	PDP (98) PDP (97-98)*		408 970	1 1	0.009-0.015 0.009-0.9	na na	0.019
	FDA	Import	255	2	0.003-0.10	na	0.003
		US	246	4	0.003-0.11	na	0.003
Carrots	PDP (94-96)		1888	0	na	na	0.027
	FDA	Import	23	0	na	na	0.003
		US	256	0	na	na	0.003
Celery	PDP (94)		176	29	0.014-0.28	0.09 (08)	0.034
	FDA	Import	3	0	na	na	0.003
		US	14	2	0.003-0.12	na	0.003
Citrus (Oranges)	PDP (94-96)		1873	0	na	na	0.020
	FDA	Import	51	0	na	na	0.003
		US	199**	0	na	na	0.003
Cottonseed	Field trials		22	6	<0.02-0.4		0.02
Cucumber	FDA (94-98 import and domestic		173	0	na	na	0.003
Eggplants	Ft		9	9	0.08-1.75	0.59	0.08
Garlic	Field trials		see onion				
Ginger	Field trials						
Honeydew	see cantaloupe						
mint	Field trials		12	0	<0.02	Na	0.02
onions	Field trials						

peanuts	Field trials 41402609 00083522		11	1	<0.02-0.04	0.000218	0.007
peppers sweet	**FDA**	Import	107	3	0.0015-0.37	0.140	0.003
		US	67	4			
peppers hot	**FDA**	Import	135	5	0.0015-0.61	0.28	0.003
		US	8	0			
Pineapples	Field trials 00113380		14	14	0.02-0.6	0.252	0.02
	FDA	Import	118	0	na	na	0.003
		US	2	0	na	na	0.003
Potatoes	PDP (94-95)		1401	0	na	na	0.025
	FDA	Import	34	0	na	na	0.003
		US	623				
Sweet Potatoes	PDP (96-97)		1202	0	na	na	0.0164
	FDA	Import	16	0	na	na	0.003
		US	41				
pumpkins	see cantaloupe						
soybeans	PDP 98		690	0	na	na	0.006
Summer squash	see cantaloupe						
Tomatoes	PDP (96-98)		1613	12	0.03-0.058	0.03	0.0188

	FDA	Import US	186 169	0	na	na	0.003
Winter Squash	see cantaloupe						
Watermelon	see cantaloupe						

* the data are from fresh winter squash, ** includes 21 grapefruit 1998